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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,928	MERCKEN ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/11/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/11/09 has been entered.

Status of Application/Amendments/claims

2. Applicant's amendment filed 3/11/09 is acknowledged. Claims 1, 12 and 13 are cancelled. Claims 2-6, 8, 9, 11, and 14-16 are amended. Claims 2-11 and 14-16 are pending in this application and under examination in this office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

4. The declaration filed on 3/11/09 under 37 CFR 1.131 (should be 37 CFR1.132) has been considered but is ineffective to overcome the US Patent No. 6984720 reference. No data was provided to support that the monoclonal antibody clone 5C4 disclosed by US 6984720 is different from the claimed clone 5C4 (J&JPRD/hAb11/2).

5. Applicant's arguments filed on 3/11/09 have been fully considered but they are not deemed to be persuasive for the reasons set forth below. In addition,

Claim Rejections/Objections Maintained

In view of the amendment filed on 3/11/09, the following rejections are maintained.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-5, 8, 9, 11 and 14-16 stand rejected under 35 U.S.C. 102 (b) as being anticipated by Walker et al (J. Neuropathol. Exp. Neurol.1994 Jul. 53: 377-383), Pirttila et al. (J. Neurol Sci. 1994 Dec 1; 127:90-5), WO0162801 (as in IDS submitted on Mar 23, 2005) or Naslund et al (as in IDS submitted on Mar 23, 2005). Claims 2, 5, 8, and 14-16 stand rejected under 35 U.S.C. 102 (b) as being anticipated by Solomon et al. (Proc. Natl. Acad. Sci. USA. 1996. 93: 452-455). Claims 2, 5, 8, and 14-16 stand rejected under 35 U.S.C. 102 (a) as being anticipated by Huse et al. (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284). These rejections are maintained for the reasons made of record.

On p. 6 of the response, Applicant argues that as discussed during the Feb 18, 2009 interview and the amendment filed on Jan 14, 2009, none of the cited references dislcose an antibody having an epitope encompassing Aβ11-15/17, a reactivity of Aβ11-x and no cross-reactivity to Aβ1-40 as presently claimed. Applicant's arguments have been fully considered but they are not persuasive.

In response, as previously made of record, the art antibodies raised against Aβ1-16 (10D5 & 6E10, Walker and Naslund), Aβ17-24 (4G8, Prittila), and Aβ13-28 (266, WO01/62801) immungens can bind to the epitopes of Aβ11-x as evidenced by Huse et al (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284, cited in the previuos office action). In addition, the antibodies raised against Aβ 1-28 and 8-17 taught by Solomon et al. would inherently recognize Aβ11-x because the amino acid sequence of the immunogens (5-7 amino acids of Aβ11-x) for the instant antibodies are encompassed within the sequences of amino acids 1-28 and 8-17 of Aβ. For the same reason, the antibody BNT77 taught by Huse et al. was raised against amino acids 11-16 of Aβ, thus it can recognize N-terminal truncated species of Aβ. If the epitope to which Applicant's antibody binds is present in Aβ11-x, so that Applicant's antibody binds to Aβ11-x, it is also present in Aβ 11-16, 1-28 and 8-17.

With regard to whether the art antibodies have the same property as the claimed antibodies that bind to Aβ11-x without cross reacting with the full length of Aβ1-40/42, it is noted that Applicant claims a product in terms of a function, property or characteristics is the same as the prior art products. Note that

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.' In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See MPEP § 2112.01 [R-3].

As previuosly made of record, if the epitope to which Applicant's antibody binds is present in Aβ11-x, so that Applicant's antibody binds to Aβ11-x, it is also present in Aβ

1-16, 17-24, and 13-28. Applicant fails to provide side-by-side comparisons to demonstrate that the claimed antibody is different from those antibodies disclosed by Walker et al., Pirtila, WO0162801 and Naslund. It is also known in the art that anti-Aβ antibodies can cross react with different species or different lengths of Aβ peptides in different titrations because of their different binding affinity. Applicant has provided no showing that the antibodies in the art have characteristics different from those specifed by Applicant and do not in fact cross react with the full length of Aβ1-40/42 in the same titration or at the same concentration as those of the prior art. Since the claimed antibody is substantially identical in structure or composition and is able to bind to Aβ11-x, the antibodies disclosed by Walker et al., Pirtila, WO0162801 and Naslund farily anticipate the claimed antibody because Applicant fails to demonstrate that the claimed antibody has a function, property or characteristics different from the antibodies dislcosed by the art.

Accordingly, the rejection of claims 2-5, 8, 9, 11 and 14-16 under 35 U.S.C. 102 (b) as being anticipated by Walker et al., Pirttila et al., WO0162801 or Naslund et al. is maintained. The rejection of claims 2, 5, 8, and 14-16 under 35 U.S.C. 102 (b) as being anticipated by Solomon et al. or by Huse et al. is maintained.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-5, 8, 9, 11 and 14-16 stand rejected under 35 U.S.C. 103(a) for being unpatentable over Huse et al. (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284) in view of Walker et al (J. Neuropathol. Exp. Neurol.1994 Jul. 53: 377-383) and WO0162801. The rejection is maintained for the reasons made of record.

On p. 7 of the response, Applicant argues that as discussed during the Feb 18, 2009 interview and the amendment filed on Jan 14, 2009, none of the cited references dislcose an antibody having an epitope encompassing Aβ11-15/17, a reactivity of Aβ11-x and no cross-reactivity to Aβ1-40 as presently claimed. Applicant's arguments have been fully considered but they are not persuasive.

In response, for the reasons set forth above in section of the 102 rejection at paragraph 6, the antibodies disclosed by Huse et al., Walker et al. and WO0162801 do recognize Aβ11-x because the antibodies disclosed Huse et al., Walker et al. and WO0162801 have been shown to have the same property as the claimed antibodies. In addition, WO0162801 also teaches a method of detection of Aβ in the brain tissue and

CSF of Alzheimer's disease patients using labeled antibodies by electrophoresis or ELISA as recited in claims 9-11 and 14 (see p.26, examples 1-2; p. 30, example 6). Thus, It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to use the antibody raised against Aβ11-16 or use the antibody that can recognize Aβ11-x to detect Aβ11-x in Alzheimer's disease because the level of Aβ11-40/42 has been shown increased in AD patients. The person of ordinary skill in the art would have been motivated and have expected success in using an antibody that recognize Aβ11-x to detect diseases associated Aβ formation because the antibody against Aβ11-16 is able to detect Aβ11-40/42 in AD brains.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of Aβ11-40 in the CSF and brain section of Alzheimer's disease by using antibodies raised against Aβ peptides consisting of 6-8 amino acids of Aβ_11 (6AA) or Aβ_(8AA) (SEQ ID NOs: 1-4), does not reasonably provide enablement for using the antibodies that specifically bind to Aβ11-x peptides to diagnose Down's syndrome as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

use the invention commensurate in scope with these claims. The rejection is reinstated and maintained for the reasons made of record.

On p. 7-8 of the response, Applicant argues that the claimed invention is enabled for diagnosing AD and Down's syndrome because amyloid deposits and plaques are the prominent pathological features of AD and Down's syndrome as compared to normal aging brains as supported by paragraphs [0004]-[0006] of the instant specification and Naslund et al. (p. 8380-8381, PNAS 1994, 91: 8378-8382) and Iwatsubo (p. 1825 & 1827, J. Pathology. 1996, 6: 1823-1830). Applicant's argument has been fully considered but it is not persuasive.

In contrast, the specification only teaches diagnosis of AD with the claimed antibody but fails to teach diagnosis of Down's syndrome as recited in instant claims 14 and 16. As previously made of record, neither the specification nor the cited prior art provides sufficient guidance as to how to diagnose Down's syndrome based on the detection of Ab11-x using the claimed antibody. The specification fails to provide guidance as to how much levels of the Aβ11-x expression would be considered as an indicator of Down's syndrome. Therefore, in view of the necessity of experimentation, the limited working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification, undue experimentation would be required by a skilled artisan to practice the claimed invention.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On p.8 of the response, Applicant argues that the specification has clearly defined the term "support" at paragraph [0065] of the published specification. Applicant's argument has been fully considered but it is not persuasive.

In contrast, as previously made of record, the specification fails to set forth the metes and bounds of what is encompassed within the definition of such support; thus the claim is indefinite. Note that

> There are two separate requirements set forth in this paragraph: (A) the claims must set forth the subject matter that applicants regard as their invention; and (B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Claim Rejections - 35 USC § 102/103

10. Claims 2, 6, 7, 15 and 16 stand rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent No. 6984720 (Korman et al. issued on Jan 10, 2006, priority Aug 24, 1999). The rejection is maintained for the reasons made of record.

On p. 8 of the response, Applicant argues that Applicant has submitted a declaration showing that the hybridoma cell line designated 5C (should be 5C4) in the '720 patent produces antibodies specific to human T cell surface molecule CTLA-4, which is different the hybridoma cell line J&JPRD/hAb11/2 (designated 5C (should be

5C4) in the present specification). Applicant's arguments have been fully considered but they are not persuasive.

In response, the declaration filed on 3/11/09 under 37 CFR 1.131 (should be 37 CFR1.132) has been considered but is ineffective to overcome the 102/103 rejection as being anticipated by US Patent No. 6984720 reference. No data was provided in the declaration to show that the monoclonal antibody clone 5C4 disclosed by US 6984720 is different from the claimed clone 5C4 (J&JPRD/hAb11/2). The declaration fails to provide data to demonstrate that the antibodies produced by the clone 5C4 in the '720 patent cannot recognize the claimed epitopes and thus is different from the claimed clone 5C4 (J&JPRD/hAb11/2).

As previously made of record, the 5C4 monoclonal antibody disclosed by the '720 patent has the same name as described in the instant specification and also can block amyloid accumulation in Alzheimer's patients (see col.9, lines 47-62.). Applicant fails to demonstrate that the 5C4 monoclonal antibody disclosed by the '720 patent is structurally and functionally different from the claimed antibody (i.e. also named 5C4 as described on p.22 of the instant specification). Applicant fails to provide side-by-side comparisons to demonstrate that the claimed antibody is structurally and functionally different from the antibodies disclosed by the '720 patent. Since the 5C4 monoclonal antibody of the '720 patent can block amyloid accumulation in AD patients, it indicates that the 5C4 monoclonal antibody of the '720 patent has the same property and function as the claimed antibody, which is capable of binding to Aβ11-x, and thus the binding of

the '720 patent's 5C4 monoclonal antibody to Aβ11-x would be an inherent feature of the antibody. Note that

"Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA1977)." See MPEP § 2112 [R-3]

In addition,

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.' In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See MPEP § 2112.01 [R-3].

Claim Rejections - 35 USC § 103

11. Claims 2-11 and 14-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Huse et al. (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284) in view of Walker et al (J. Neuropathol. Exp. Neurol.1994 Jul. 53: 377-383 as cited in the previous office action) and WO0162801 (as in IDS submitted on Mar 23, 2005 and cited in the previous office action) as applied to claims 2-5, 8, 9, 11 and 14-16 above, and further in view of US Patent No. 6984720 (Korman et al. issued on Jan 10, 2006, priority Aug 24, 1999). The rejection is maintained for the reasons made of record.

On p. 9 of the response, Applicant argues that as discussed during the Feb 18, 2009 interview and the amendment filed on Jan 14, 2009, none of the cited references dislcose an antibody having an epitope encompassing Aβ11-15/17, a reactivity of Aβ11-

x and no cross-reactivity to Aβ1-40 as presently claimed. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, for the reasons set forth above in section of the 102 & 103 rejections at paragraphs 6-7, the antibodies disclosed by Huse et al., Walker et al. and WO0162801 do recognize Aβ11-x because the antibodies disclosed Huse et al., Walker et al. and WO0162801 have been shown to have the same property as the claimed antibodies. In addition, WO0162801 also teaches a method of detection of Aβ in the brain tissue and CSF of Alzheimer's disease patients using labeled antibodies by electrophoresis or ELISA as recited in claims 9-11 and 14 (see p.26, examples 1-2; p. 30, example 6). In addition, the '720 patent teaches a monoclonal antibody named 5C4 that is capable of blocking amyloid accumulation in AD patients, which has the same name of J&JPRD/hAβ11/1 and J&JPARD/hAβ11/2 as described in the instant specification. Thus, it is obvious to a skilled artisan at the time the instant invention was made to generate an antibody raised against Aβ11-15 or 11-17 (SEQ ID NO:1-4) to substitute the antibodies of Huse et al., Walker et al., and WO0162801 by a hybridoma 5C4 (J&JPARD/hAβ11/2) as in instant claims 6-7 because the antibody of the hybridoma 5C4 can reduce amyloid accumulation, and antibodies against Aβ 1-16, 11-16, 1-28 and 8-17 can bind Aβ11-x. It is also obvious to substitute the antibodies of Huse et al., Walker et al., and WO0162801 by a hybridoma cell line named 5C4 (J&JPARD/hAβ11/2) in the methods of detecting or diagnosing AD to detect Aβ11-x in AD as recited in instant claim 10 because the antibody of the hybridoma 5C4 can

reduce amyloid accumulation and the level of Aβ11-40/42 has been shown increased in AD patients.

Conclusion

12. NO CLAIM IS ALLOWED.

13. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
May 19, 2009

/Christine J Saoud/

Primary Examiner, Art Unit 1647